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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/064,392	07/09/2002	John Hefti	JH-003	5837

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EXAMINER	
GAKH, YELENA G	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/064,392	HEFTI, JOHN	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *14-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 8 and 11-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment filed on 07/20/08 is acknowledged. Claims 1-31 are pending in the application. Claims 5-7, 9-10 and 13 are cancelled. Claims 14-31 are withdrawn from consideration. Claims 1-4, 8 and 11-12 are considered on merits.

Response to Amendment

2. In response to the amendment of the claims rejections of the pending claims under 112, second paragraph and the prior art are modified and rejection of claim 2 under 112, second paragraph is added.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. According to MPEP:

> **2163.02 Standard for Determining Compliance With the Written Description Requirement.** The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).
> Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in

> possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

The instant specification fails to adequately disclose embodiments for the method, wherein the step of supplying a reactive constituent comprises supplying a second concentration of the bio/chemical species to the finite volume diffusion channel, especially when the reactive constituents are supposed to be immobilized (fixed) within the diffusion channel, while the bio/chemical species are supposed to be diffused trough the channel (Claim 2). Therefore, the Applicant failed "to convey with reasonable clarity to those skilled in the art that, as of the filing date sought" that he "was in possession of the invention, and that the invention, in that context, is whatever is now claimed".

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8 and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Presently amended claim 1 recites the method comprising supplying bio/chemical species to a diffusion channel and then depositing a reactive constituent at a stationary position. In light of the amendment, which requires the reactive constituent to be fixed at the stationary position, it becomes unclear, as to how it is possible to first supply bio/chemical species to the channel, and then deposit the reactive constituent at the stationary position inside the channel? The steps seem to be recited in a reverse order.

Furthermore, it is not apparent, what the expression "obtaining a differential measurement between the first and second measurement probes, wherein said obtained differential measurement corresponds to a diffusion response occurring between the bio/chemical species and the reactive constituent along the transport axis and between the first and second measurement probes". With the reactive constituents being fixed at a certain stationary position between the first and the second probes, it is not apparent, as to which "diffusion response occurring between the bio/chemical species and the reactive constituent along the transport axis" the claim recites? In general, what is the "diffusion response"? The expression does not seem to be clear. The examiner considers the claim as reciting detection at two probes for the bio/chemical species before and after interacting with the reactive constituents.

The same questions arise for claim 8.

Claim 2 is not clear. It is not apparent, as to how supplying a reactive constituent can comprise supplying a second concentration of the bio/chemical species to the diffusion channel? First, it is not clear, as to how the reactive constituent is related to the bio/chemical species in regards to their supplying to the channel? Are they supplied in the same flow? Second, it is not apparent, as to how the reactive species is supposed to be supplied with the bio/chemical species, if the reactive species are to be fixed within the channel, according to claim 1?

Further, the steps of depositing and fixing the reactive constituent recited in claims 1 and 8 are not analogous to the step of supplying a reactive constituent to the diffusion channel recited in claims 2-4 and 11-12. The step of supplying the reactive constituent to the diffusion channel appears to be similar to the step of supplying the bio/chemical sample to the diffusion channel. Therefore, if the bio/chemical sample is supplied to the diffusion channel as a flow, similar supplying of the reagent constituent as a flow can be assumed from claims 2-4 and 11-12. However, claims 1 and 8 recite that the reaction constituent is supposed to be fixed at specific locations within the diffusion channel. Thus, there is a certain contradiction in the recitation of claims 2-4 and 11-12 and the parent claims 1 and 8.

Furthermore, claims 3 and 11 recite ionic species. It is unclear, as to how the ionic species are related to the bio/chemicals? Should bio/chemicals be ionic in order to interact with the ionic species?

It also unclear as to how "small molecules indented for therapeutic purposes" relate to the population cells. Are the population cells the specific disease cells?

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. **Claims 1-4, 8 and 11-12** are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansmann et al. (US 5,952,173) (Hansmann) in view of Yager (US 6,007,775).

Hansmann discloses:

> "The present invention relates to analytical devices for determining the presence or an amount of an analyte in a test sample comprising an array of structures wherein the structures have a surface providing a site for immobilizing reagent. The immobilized reagent is covalently or non-covalently attached to said surface of the structures and is capable of binding an analyte, analyte-analog, ancillary binding member, or a labelled reagent. The analytical devices of the present invention also comprise a plurality of channels wherein a test sample containing an analyte, analyte-analog, ancillary binding member, or labelled reagent can flows through the channels and the analyte, analyte-analog, ancillary binding member, or labelled reagent can diffuse across the width of said channels thereby binding to the immobilized reagent. The labelled reagent comprising a specific binding member conjugated to a detectable label wherein the detectable label produces a signal determining the presence or amount of the analyte present in the test sample." (Summary of the Invention).

> "Assays performed in the devices of the present invention optimize capture at the surface of the structure. By utilizing the methods taught herein, tight control of the capture site geometry

improves the uniformity and efficiency of capture. The narrow, deep channels and the large surface area of the structures provides for diffusion of analyte and enhanced analyte capture. The channel design is based on diffusion of an entity in the test sample to interact with immobilized reagent on the surface of the structures. Typically, the entity is randomly distributed in the cross section of the channel. The entity diffuses to the structure surface where the entity can interact with immobilized reagent.

Immobilized reagent can be covalently or non-covalently attached onto the surface of the structures as well as within the capillaries and/or chambers. The reagent can be applied as a time-released reagent, spatially separated reagent, or coated and dried onto the surface. Such techniques of placing immobilized reagent on the surfaces are well known to those skilled in the art." (col. 9, lines 52-67, col. 10, lines 1-3).

Regarding claims 3-4 and 11-12 Hansmann discloses:

"A polyanionic material is coupled to a mix of monoclonal anti-HIV antibodies which are specific to HIV antigen common to both HIV-1 and HIV-2. The polyanionic material is placed on the surface of a chamber anterior to the structures of the device. The structures are treated with a cationic solution, such as polyglutamic acid.

(117) A test sample containing HIV antigen common to both HIV-1 and HIV-2 is added to the inlet port of the device where it is transported by capillary action to the chamber. The test sample is mixed with the antibodies coupled to the polyanionic material whereby test sample HIV antigen common to both HIV-1 and HIV-2 will specifically bind to the antibodies. Capillary action transports the HIV antigen-anti-HIV antibody-polyanion complex out of the chamber and into the array of structures.

(118) The polyanionic material will be captured by the cationic material on the surfaces of the structures. Fluorescent (fluorescein) labelled particles coupled to anti-HIV antibodies which are specific to HIV antigen common to both HIV-1 and HIV-2 are added to the inlet port of the device. Capillary action transports the labelled particles coupled to anti-HIV antibodies to the structures of the device where they will bind to HIV antigen common to both HIV-1 and HIV-2 which are captured at the capture site.

(119) The fluorescent labelled particles coupled to anti-HIV antibodies will accumulate at the capture site in proportion to the amount of test sample HIV antigen common to both HIV-1 and HIV-2." (col. 19-20, Example 7).

Hansmann does not specifically disclose two measurement probes along the longitudinal transport axis at the first and second locations, wherein the reagents are immobilized in-between these two locations, or measuring the rate of reaction.

Yager teaches multiple probes (electrodes) within the diffusion channel for detecting difference in the measurements of the analyte diffused along the transport axis upon its

interaction with the reagent within the channel (col. 4, lines 48-58) and deducing the rate of reaction (col. 7, lines 21-29).

It would have been obvious for a person of ordinary skill in the art to modify Hansmann's method by utilizing at least two probes disclosed by Yager for detecting difference in measurements for the analyte, which diffuses through the transport axis of the diffusion channel and interacts with the corresponding reactive constituents, because it gives an accurate estimation of the extent of the analyte (bio/chemical species) interaction with the reagent, including determining reaction kinetics. It would have been obvious for a person of ordinary skill in the art to compare such differential measurement to a predetermined value, because comparing measurements for the analyte with a predetermined value is a conventional methodology in analytical chemistry.

Response to Arguments

9. Applicant's arguments with respect to claims 1-4, 8 and 11-12 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

9/18/2008